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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,027	08/04/2000	Ranjit Banerjee		2670

7590
Arthur I Degenholtz
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06/03/2002

EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,027

Applicant(s)

R. BANERJEE

Examiner

Ethan C. Whisenant

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. The applicant's Response to the Office Action has been entered. The applicant's response was received on 23 APR 02 and has been entered as paper no. 19. The claim(s) pending in this application is/are **Claim(s) 2-8**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

SEQUENCE RULES

2. This application still fails to comply with the requirements of 37 CFR 1.821 through 1.825. The CRF was technically flawed and could not be entered into the database. See the Notice to Comply with the Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

CLAIM OBJECTIONS

3. **Claim(s) 4** is /are objected to for the following minor informality. The word "complementary" is misspelled as "complimentary"

35 USC § 112- 2ND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

5. **Claim(s) 2-8** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim(s) 2-4 is/are indefinite in that it is unclear as to the composition of Buffer(s) A, B, C and/or D. *If the applicant were to cancel Claims 5-8 and bringing those limitations in Claims 5-8 into Claims 1-4 this portion of the 112, 2nd paragraph rejection will be overcome.

Claim 4 is indefinite because the phrase "the protein extract " lacks proper antecedent basis.

What follows is a proposed examiner's amendment that the examiner believes will bring the claims into condition for allowance.

Proposed Examiner's Amendment

Claim 2 (proposed) A method for the simultaneous isolation of biologically active transcription factors and DNA, wherein no ultracentrifugation or sonication is used, comprising the following steps:

- a) collect cells from a culture or from a patient,
- b) washing said cells at least once with PBS,
- c) suspend and maintain said cells in buffer A (cell lysis buffer) for approximately 15 minutes wherein buffer A comprises : 20mM Hepes, pH 7.9, 10 mM NaCl, 3mM MgCl₂, 0.1% NP-40, 10% glycerol, 0.2 mM EDTA, 1 mM DTT, 0.4 mM PMSF, 1 ug/ml antipain and 1 ug/ml leupeptin,
- d) centrifuge the suspension of step c at approximately 2,000 rpm for approximately 5 minutes at approximately 4°C,
- e) remove the upper cytoplasmic supernatant fraction and then clarify this fraction by adding buffer D (cytoplasmic extraction clarification buffer) at approximately 4°C, wherein buffer D comprises : 20mM Hepes, pH 7.9, 400 mM NaCl, 0.2 mM EDTA, 40% glycerol, 1 mM DTT, 0.4 mM PMSF, 1 ug/ml antipain and 1 ug/ml leupeptin,
- f) centrifuge the clarified fraction formed in step e at approximately 13,000 rpm for approximately 15 minutes,
- g) remove and freeze the top clear supernatant on dry ice then store the frozen top clear supernatant at approximately -86°C,
- h) wash the bottom nuclear fraction formed at the end of step d with buffer B (extraction buffer without salt) wherein buffer B comprises : 20mM Hepes, pH 7.9, 0.2 mM EDTA, 20% glycerol, 1 mM DTT, 0.4 mM PMSF, 1 ug/ml antipain and 1 ug/ml leupeptin,
- i) centrifuge the solution formed in step h at approximately 2,000 rpm for approximately 5 minutes, at approximately 4°C, thereby pelleting cellular nuclei,
- j) suspend the pelleted nuclei of step i in buffer C (extraction buffer with salt) on ice tapping the suspended mixture for approximately 45 minutes whereby nuclear proteins are extracted, wherein buffer C comprises : 20mM Hepes, pH 7.9, 400 mM NaCl, 0.2 mM EDTA, 20% glycerol, 1 mM DTT, 0.4 mM PMSF, 1 ug/ml antipain and 1 ug/ml leupeptin,
- k) centrifuge the mixture formed in step j at approximately 15,000 rpm for approximately 15 minutes, at approximately 4°C,
- l) remove the top clear supernatant comprising biologically active transcription factors from the bottom nuclear fraction containing nucleic acids,
- n) extract DNA from said bottom nuclear fraction.

In **Claim 3** change "step 16" on line 3 to "step *l*"

In **Claim 4** Change the claim to read "The method of claim 2 wherein the method further includes the step of analyzing the biologically active transcription factors present in the top clear supernatant of step *l*."

Cancel **Claims 5-8**

CONCLUSION


6. Claim(s) 2-8 is/are rejected and/or objected to for the reason(s) set forth above.

7. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.


ETHAN C. WHISENANT
PRIMARY EXAMINER